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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,143	03/19/2001	Guenter Schultz	1/1128	9439
28501	7590	03/30/2004		
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877			EXAMINER WEGERT, SANDRA L	
			ART UNIT 1647	PAPER NUMBER

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,143

Applicant(s)

SCHULTZ ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Sequence Rules

The instant application is not fully in compliance with the sequence rules, 37 CFR 1.821-1.825, because each disclosure of a sequence embraced by the definitions set forth in the rules is not accompanied by the required reference to the relevant sequence identifier (i.e., SEQ ID NO:). This occurs in Claims 13-20, for example.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-28, 38, 51, 53, 54 and 56-61, drawn to nucleic acids encoding an OTRPC4 polypeptide, complementary nucleic acids, vectors, host cells, and methods of producing polypeptides recombinantly, classified in class 435, subclass 69.1+.
- II. Claims 29-37 and 55, drawn to an OTRPC4 channel protein, classified in class 530, subclass 350+.
- III. Claims 39 and 40, drawn to an antibody against an OTRPC4 polypeptide and method of making an antibody, classified in class 424, subclass 130.1+.
- IV. Claims 41-47, drawn to a method of detecting a modulator or ligand of an OTRPC4 polypeptide, classification dependent upon structure of recited compound.

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- V. Claims 48 and 50, drawn to an agonist or transductional activator of an OTRPC4 channel, and composition, classification dependent on structure of recited compound.
- VI. Claims 49 and 50, drawn to an antagonist or transductional blocker of an OTRPC4 channel, and composition, classification dependent on structure of recited compound.
- VII. Claims 52 and 54, drawn to a ribozyme and composition, classified in class 435, subclass 183+.
- VIII. Claims 62-67, drawn to a transgenic non-human animal and methods of producing the animal, classified in class 800, subclass 8+

Secondary Election/Restrictions

Furthermore, applicant is required to elect **one** polynucleotide sequence by referring to SEQ ID NO: (note: a SEQ ID NO will need to be associated with the polynucleotide sequence elected for prosecution; see the above objection concerning *Sequence Rules*).

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is

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deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I-III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The nucleic acid of Inventive Group I can be used in gene therapy as well as in the production of the protein of interest. The protein of Group II can be used other than to make the antibody of Group III, such as used as a probe, or used therapeutically.

Furthermore, Inventive Groups I and II are related as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)). In the instant case the polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Invention I is unrelated to Inventions IV-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide of Group I is neither used in nor produced by any of Inventions IV-VII.

Invention I, if related to Invention VIII, may be related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

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product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polynucleotide of Group I can be used as a probe. However, Invention I is essentially unrelated to Invention VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide product of Group I is not used in the same methods as an animal comprising the polynucleotide.

Invention II is related to Inventions IV-VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the OTRPC4 channel can be used for other than to search for ligands, such as to generate antibodies.

Invention II is unrelated to Inventions VII and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of Group II are not disclosed as used in the same methods as Inventions VII and VIII.

Invention III is unrelated to Inventions IV-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Group III are not disclosed as used in the same

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methods as Inventions IV-VIII. Furthermore, the antibody of Group III is neither used in nor produced by any of Inventions IV-VIII.

The methods of Inventions I, III, IV and VIII are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals. Likewise, Invention IV is related to Inventions V and VI as a process of detecting a compound and the product detected. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to find other and materially different product or (2) that the product as claimed can be detected by another and materially different process (MPEP § 806.05(f)). In the instant case a ligand of the OTRPC4 channel could be identified by chemical modification and testing of structurally related compounds.

Furthermore, Invention IV is unrelated to the products of Inventions VII and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the Inventions are not disclosed as capable of use together.

Inventions V-VIII are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The agonist of Invention V has a different structure and function than the antagonist of Invention VI. The

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ribozyme of Group VII is used catalytically, while the transgene animal of Invention VIII can be used to study the physiological function of the transporter peptide.

Furthermore, each polynucleotide sequence in Claims 13-20 represents a patentably distinct invention. The polynucleotide sequences in Claims 13-20 are distinct, each from the other, because they have different putative functions, different structures, and require completely different search terms, starting points and strategies.

Because these inventions are distinct for the reasons given above and the search required for each group is unique, and because each nucleic acid of Claims 13-20 requires a completely separate search, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Inventive Groups I-VIII and must additionally elect one SEQ ID NO:. Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

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Advisory information

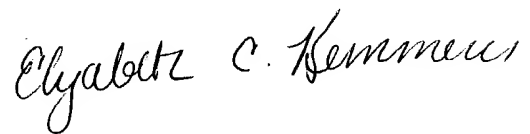
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

23 March 2004



ELIZABETH KEMMERER
PRIMARY EXAMINER